

Applicants: Samuel C. Silverstein et al.
Serial No.: 09/658,698
Filed : September 8, 2000
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In the Figures

Please replace Figures 1 to 4B of the subject application with corrected Figures 1 to 4B annexed hereto as **Exhibit B**.

REMARKS

Claims 1-32 are pending in the subject application. No claims have been added, cancelled or amended by this Amendment. Applicants have submitted a substitute abstract and corrected Figures 1 to 4B in order to introduce certain formatting changes. Applicants submit that the substitute abstract and the corrected Figures do not introduce any new matter. Accordingly, claims 1-32 will still be pending and under examination upon entry of this Amendment.

Applicants annex hereto as Exhibit C a marked-up version of the abstract to show the changes made relative to the previous version thereof.

In view of the arguments below, applicants maintain that Examiner's rejections have been overcome and respectfully request that they be withdrawn.

Formalities

Drawings

The Examiner objected to Figures 1-4B as allegedly not compliant with 37 C.F.R. §1.84 or §1.152 as indicated by a September 20, 2002 Notice of Draftspersons's Patent Drawing Review. A copy of the September 30, 2002 Notice is attached hereto as **Exhibit D**.

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Specifically, the Notice indicated that Figures 1-4B allegedly contain numbers and reference characters not oriented in the same direction as the view.

In response, applicants have annexed hereto corrected Figures 1 to 4B as **Exhibit B**.

In view of the above remarks, applicants respectfully request that the Examiner withdraw the objection to the figures.

Abstract

The Examiner objected to the abstract of the disclosure under M.P.E.P. §608.01(b). Specifically, the Examiner asserts that it is not clear what the subject of the third sentence of the abstract is. In response to the Examiner's objection, applicants have annexed hereto a substitute abstract as **Exhibit A**. The substitute abstract addresses the Examiner's concern.

Rejection Under 35 U.S.C. §112, First Paragraph

The Examiner rejected claims 1-32 under 35 U.S.C. §112, first paragraph, as allegedly not enabled.

In response, applicants respectfully traverse the Examiner's rejection.

The test for enablement is whether one skilled in the art could, at the time of the invention, make and use the claimed invention based on the disclosure and information known in the art without undue experimentation. Applicants maintain that the claimed invention satisfies the test for enablement, and that the

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Examiner has not set forth sufficient grounds for concluding otherwise.

Briefly, the rejected claims provide methods for delivering an antigen to a Class I MHC receptor to induce immunity against the antigen in a subject having a disease. The claimed invention is based on applicants' surprising discovery that antigen-filled particles will bind to ligand-binding antigen-presenting cells (APCs) permitting the APC phagolysomes to ingest the Ag-particles to facilitate transfer of the ingested antigen from the phagolysomes into the cytoplasm.

In support of the rejection, the Examiner asserts that applicants have provided insufficient guidance and direction regarding the effectiveness of any of the recited administered cells in delivering an antigen to a Class I MHC receptor to induce immunity against the antigen in a subject. Specifically, the Examiner asserts that applicants have only provided a limited number of prophetic examples to determine the effectiveness of the recited methods and cites Koppleman et al. for the proposition that it would require undue experimentation to determine if any antigen would be presented in a Class I-restricted fashion.

Applicants disagree with the Examiner's position. First, applicants note that the specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art would be able to practice it without undue experimentation. The Examiner's reliance on Koppleman et al. does not support the Examiner's position that the specification does not enable the claims. Applicants submit that Koppleman et al., at most suggest that some selectivity is

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involved regarding subsequent processing of peptides in the ER. This selectivity, if it in fact exists, does not necessitate undue experimentation in practicing the claimed invention. Second, applicants note that the specification does indeed teach a working example of this invention. Specifically, the specification discloses a procedure for the loading of a peptide into red blood cell ghosts; delivery of the peptide to a Class I MHC receptor; and subsequent induction of cytotoxic CD8 lymphocytes. Such teaching can be found at, *inter alia*, pages 32-35 of the specification.

In view of the above remarks, applicants respectfully request that the Examiner withdraw the rejection of claims 1-32 under 35 U.S.C. §112, first paragraph.

Conclusion

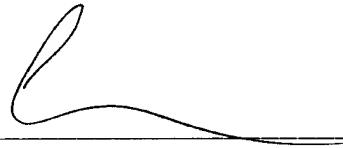
Applicants maintain that claims 1-32 are in condition for allowance, and thus, allowance is respectfully requested.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

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No fee is deemed necessary in connection with the filing of this Amendment. However, if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,



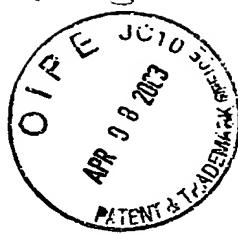
I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

7/2/03 Date

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EXHIBIT
C



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APR 14 2003

Marked-up Version of the Abstract to Show Changes

TECH CENTER 1600/2900

A NOVEL METHOD FOR USING PHAGOCYTIC PARTICLES AND ATP RECEPTORS
TO DELIVER ANTIGENS TO MHC CLASS I RECEPTORS TO INDUCE IMMUNITY
AGAINST MICROBIAL PATHOGENS OR TUMORS OR TO SUPPRESS IMMUNITY

Abstract of the Disclosure

This invention provides methods of delivering an antigen to an Class I or Class II MHC receptors to induce immunity against the antigen in a subject having a disease. This invention also provides methods of delivering an antigen to an Class II or class I MHC receptor to supress immunity against the antigen in a subject having a disease. [the ligand-binding APCs to bind to the ligand-coated Ag/ATP-filled particles and APC phagolysosomes to ingest the ligand-coated Ag/ATP-filled particles to facilitate transfer of the ingested antigen from the phagolysosomes into cytoplasm such that the antigen is delivered to a Class II MHC receptor and is expressed on the surface of the APCs (Ag-APCs); d) incubating the Ag-APCs of step (c) with lymphocytes previously removed from the subject having the disease; and e) administering the incubated lymphocytes of step (d) to the subject so as induce Class II MHC presentation and elicit suppressor T-lymphocytes so to supress immunity against the antigen in the subject.]

EXHIBIT

D



ITEM P TO 948 (Rev. 03/02)

U.S. DEPARTMENT OF COMMERCE - Patent and Trademark Office

Application No. 09/686698NOTICE OF DRAFTSPERSON'S
PATENT DRAWING REVIEW

RECEIVED

APR 14 2003

The drawing(s) filed (insert date) 9/8/02 are:

- A. approved by the Draftsperson under 37 CFR 1.84 or 1.152.
B. objected to by the Draftsperson under 37 CFR 1.84 or 1.152 for the reasons indicated below. The Examiner will require submission of new, corrected drawings when necessary. Corrected drawing must be submitted according to the instructions on the back of this notice.

| | |
|--|---|
| 1. DRAWINGS. 37 CFR 1.84(a): Acceptable categories of drawings: Black ink. Color. <input type="checkbox"/> Color drawings are not acceptable until petition is granted. Fig(s) _____ | 8. ARRANGEMENT OF VIEWS. 37 CFR 1.84(i) <input type="checkbox"/> Words do not appear on a horizontal, left-to-right fashion when page is either upright or turned so that the top becomes the right side, except for graphs. Fig(s) _____ |
| 2. PHOTOGRAPHS. 37 CFR 1.84(b) <input type="checkbox"/> 1 full-tone set is required. Fig(s) _____ <input type="checkbox"/> Photographs may not be mounted. 37 CFR 1.84(c) <input type="checkbox"/> Poor quality (half-tone). Fig(s) _____ | 9. SCALE. 37 CFR 1.84(k) <input type="checkbox"/> Scale not large enough to show mechanism without crowding when drawing is reduced in size to two-thirds in reproduction. Fig(s) _____ |
| 3. TYPE OF PAPER. 37 CFR 1.84(e) <input type="checkbox"/> Paper not flexible, strong, white, and durable. Fig(s) _____ <input type="checkbox"/> Erasures, alterations, overwritings, interlineations, folds, copy machine marks not accepted. Fig(s) _____ <input type="checkbox"/> Mylar, velum paper is not acceptable (too thin). Fig(s) _____ | 10. CHARACTER OF LINES, NUMBERS, & LETTERS. 37 CFR 1.84(l) <input type="checkbox"/> Lines, numbers & letters not uniformly thick and well defined, clean, durable, and black (poor line quality). Fig(s) _____ |
| 4. SIZE OF PAPER. 37 CFR 1.84(f): Acceptable sizes: <input type="checkbox"/> 21.0 cm by 29.7 cm (DIN size A4) <input type="checkbox"/> 21.6 cm by 27.9 cm (8 1/2 x 11 inches) <input type="checkbox"/> All drawing sheets not the same size. Sheet(s) _____ <input type="checkbox"/> Drawings sheets not an acceptable size. Fig(s) _____ | 11. SHADING. 37 CFR 1.84(m) <input type="checkbox"/> Solid black areas pale. Fig(s) _____ <input type="checkbox"/> Solid black shading not permitted. Fig(s) _____ <input type="checkbox"/> Shade lines, pale, rough and blurred. Fig(s) _____ |
| 5. MARGINS. 37 CFR 1.84(g): Acceptable margins: Top 2.5 cm Left 2.5cm Right 1.5 cm Bottom 1.0 cm SIZE: A4 Size Top 2.5 cm Left 2.5 cm Right 1.5 cm Bottom 1.0 cm SIZE: 8 1/2 x 11 Margins not acceptable. Fig(s) _____ <input type="checkbox"/> Top (T) _____ Left (L) _____ <input type="checkbox"/> Right (R) _____ Bottom (B) _____ | 12. NUMBERS, LETTERS, & REFERENCE CHARACTERS. 37 CFR 1.84(p) <input type="checkbox"/> Numbers and reference characters not plain and legible. Fig(s) _____ <input checked="" type="checkbox"/> Figure legends are poor. Fig(s) _____ <input checked="" type="checkbox"/> Numbers and reference characters not oriented in the same direction as the view. 37 CFR 1.84(p)(1) Fig(s) <u>1-43</u> <input type="checkbox"/> English alphabet not used. 37 CFR 1.84(p)(2) Figs _____ <input type="checkbox"/> Numbers, letters and reference characters must be at least .32 cm (1/8 inch) in height. 37 CFR 1.84(p)(3) Fig(s) _____ |
| 6. VIEWS. 37 CFR 1.84(h) REMINDER: Specification may require revision to correspond to drawing changes. Partial views. 37 CFR 1.84(h)(2) <input type="checkbox"/> Brackets needed to show figure as one entity. Fig(s) _____ <input type="checkbox"/> Views not labeled separately or properly. Fig(s) _____ <input type="checkbox"/> Enlarged view not labeled separately or properly. Fig(s) _____ | 13. LEAD LINES. 37 CFR 1.84(q) <input type="checkbox"/> Lead lines cross each other. Fig(s) _____ <input type="checkbox"/> Lead lines missing. Fig(s) _____ |
| 7. SECTIONAL VIEWS. 37 CFR 1.84(h)(3) <input type="checkbox"/> Hatching not indicated for sectional portions of an object. Fig(s) _____ <input type="checkbox"/> Sectional designation should be noted with Arabic or Roman numbers. Fig(s) _____ | 14. NUMBERING OF SHEETS OF DRAWINGS. 37 CFR 1.84(i) <input type="checkbox"/> Sheets not numbered consecutively, and in Arabic numerals beginning with number 1. Sheet(s) _____ |
| | 15. NUMBERING OF VIEWS. 37 CFR 1.84(u) <input type="checkbox"/> Views not numbered consecutively, and in Arabic numerals, beginning with number 1. Fig(s) _____ |
| | 16. CORRECTIONS. 37 CFR 1.84(w) <input type="checkbox"/> Corrections not made from prior PTO-948 dated _____ |
| | 17. DESIGN DRAWINGS. 37 CFR 1.152 <input type="checkbox"/> Surface shading shown not appropriate. Fig(s) _____ <input type="checkbox"/> Solid black shading not used for color contrast. Fig(s) _____ |

COMMENTS

REVIEWER S. Zelik DATE 9/10/02 TELEPHONE NO. _____ATTACHMENT TO PAPER NO. 10